



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

JUN 18 1999

4101 '99 JUN 21 A9:53

Mr. Randal R. Buresh
President
Oregon's Wild Harvest
43464 S.E. Phelps Road
Sandy, Oregon 97055

Dear Mr. Buresh:

This is in response to your letter to the Food and Drug Administration (FDA) received on June 15, 1999 responding to our letter of May 27, 1999 concerning your May 18, 1999 submission pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your current letter states that Oregon's Wild Harvest is making the following statement for its product Ginger: "Eases Discomfort Associated with Travel."

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to prevent, treat, or mitigate disease, namely, motion sickness. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.
Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200
FDA, Seattle District Office, Office of Compliance, HFR-PA340

975-0163

LET281

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cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (File)

HFS-450 (file, r/f)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-605 (Bowers)

GCF-1 (Nickerson, Dorsey)

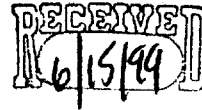
HFV-228 (SBenz)

f/t:HFS-456:rjm:6/16/99:docname:65656.adv:disc38



Oregon's Wild Harvest

June 11, 1999



Office of special Nutritionals (HFS-450)
Center for Food safety and Applied Nutrition
Food and Drug Administration
200 C street
Washington, D.C. 20204

Notification of Statements of Nutritional Support

This notification is filed pursuant to section 403 (r) (6) of the federal Food, drug, and Cosmetic Act (FTC Act), 21 U.S.C. ss 343 (r) (6). Please see attachment for a listing of dietary supplements and corresponding statement of nutritional support.

These statements are being accompanied by the required disclaimer pursuant to Section 403 (r) (6) (C) of the Act.

Statements of nutritional support are based on data which render these statements substantiated, truthful and non-misleading

Two copies of this letter and its attachment are enclosed.

Sincerely,

Randal R Buress
President

Also see docket 975-0163

Dietary Supplement	Brand Name	Statement of Nutritional Support
	Oregon's Wild Harvest	
Echinacea purpurea	Echinacea purpurea	Seasonal support for the body's natural defense system
Hawthorn berry, leaf	Cardio-Flo	Nutritional Heart Support
Siberian Ginseng, Astragalus	Energy Blend	Nutritional Stamina Support
Kava and Valerian root	Muscle Relax	Relaxes Muscle Tension
Vitex Berry, Dong Quai	Woman's Monthly	Supports Female Balance
Horse Chestnut	Horse Chestnut	Vascular Support for Legs
Marshmallow, Peppermint	Digestum	Digestive System Support
St. John's Wort-Kava	St. John's Wort-Kava	Relaxation support
Bromoflex	Bromovlex	Joint & Connective Tissue Support
Ginger	Ginger	Eased Discomfort Associated With Travel